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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/189,130 11/10/98 HOUCK J 47.653.1

021874 HM12/0306
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EXAMINER

BORIN, M

ART UNIT	PAPER NUMBER
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1631

DATE MAILED:

03/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/189,130

Applicant(s)

Houck et al.

Examiner

Michael Borin

Group Art Unit

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☒ Responsive to communication(s) filed on Dec 7, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1 and 4-23 is/are pending in the application.

Of the above, claim(s) 9-23 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 and 4-8 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Status of Claims

1. Amendment filed 12/07/2000 is acknowledged. Claims 24-31 are canceled. Claims 1, 4-23 are pending. Claims 9-23 remain withdrawn from further consideration. Claims 1,4-9 are under consideration.

2. Claim 1 remains rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C.103(a) as obvious over Kermode. The rejection is maintained for the reasons of record.

Applicant maintains that "the present invention is drawn to the anti-inflammatory properties of f-Met-Leu-Phe-Phe". The instant claim is drawn not to particular properties of the peptide, but to a pharmaceutical composition comprising said peptide. As for the dose range which, as applicant argues, the dosage range is not claimed.

Applicant further argues that f-Met-Leu-Phe-Phe composition of the instant invention has some unexpected use due to its anti-inflammatory properties. However, first, arguments related to the intended use of the composition are of little relevance in determining the patentability of the composition. *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974). Suggested use limitations do not impart patentability to composition claims where the composition is otherwise anticipated by the prior art. Second, as explained in the rejection in regard to "unexpected" property of the claimed composition as having anti-inflammatory effect, the essential difference in the effect of a biological

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mediator (such as chemotactic f-Met peptide) when it is used alone as compared to its use in the presence of another pro-inflammatory agent. Cellular response to f-Met peptides (which can be described as inflammatory response) is the same type of protective reaction which mediates response of the organism to a foreign infection. It is well known in the art that biological mediators such as chemotactic factors stimulate the migration of neutrophils from circulation into sites of infection or tissue damage. These mediators are also believed to increase cell adhesion to injured sites and to activate neutrophils to release toxic agents such as oxygen metabolites and proteases. Thus, in the presence of a provoked infection the response caused by f-Met peptides have protective, anti-inflammatory function. The rejection further provides an example of colony-stimulating factor which, similarly to f-met peptides, can be either pro- or anti-inflammatory. Lack of comment to this example is understood as a silent agreement with Examiner's analysis.

As for the use of f-Met-Leu-Phe-Phe, it is noted that applicants contend that the peptide does not have pro-inflammatory effect by itself, which is different from the action of f-Met-Leu-Phe. However, Gleisner teaches that even the latter peptide f-Met-Leu-Phe (which, as argued by applicant, is a pro-inflammatory agent) inhibits mast cell degranulation and histamine release. Examiner has no reason to expect that f-Met-Leu-Phe-Phe which is demonstrated in Kermode as one of the most effective formyl Met peptides will not have effect similar to f-Met-Leu-Phe.

The Declaration of Dr. Clagett is noticed. Even though the declaration shows the effect of fMLPP alone, it is not sufficient to overcome the rejection as the claims are drawn to a composition,

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not to a particular method of use, and the reference teaches composition which reads on the composition as claimed.

Further, applicant argues that the action of composition can be anticipated or made obvious because immune system is a highly complex system. Once again, the claims are not drawn to a particular method of use, but to a composition which is described in the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure and composition, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Where the claimed and prior art products are identical or substantially identical in composition, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 195 USPQ 430, 433 (CCPA 1977). Arguments related to the intended use of the composition are of little relevance in determining the patentability of the composition. *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974). Suggested use limitations do not impart patentability to composition claims where the composition is otherwise anticipated by the prior art. In addition, the knowledge that formyl peptides stimulate various functions of neutrophils which constitute defense reaction to infectious microorganisms would be a sufficient motivation to an artisan to apply such agent as a pharmaceutical under conditions when therapeutic stimulation of such defense reaction to infectious microorganisms is required.

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3. Rejection of claims 1, 4-8 under 35 U.S.C. 103(a) as being unpatentable over Kermode, as applied to claim 1 in the rejections above, and further in view of Goodman and Gilman, is maintained for the reasons of record. Applicant's arguments are noted but are not deemed to be persuasive.

Conclusion.

4. No claims are allowed

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If

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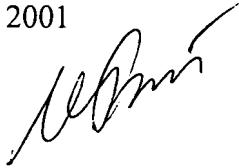
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attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward can be reached on (703) 308-0254. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February 20, 2001

mlb



MICHAEL WOODWARD, PhD
PATENT EXAMINER